

REMARKS

The May 13, 2003 Official Action and the references cited therein have been carefully considered. In view of the amendment submitted hereinwith and these remarks, favorable reconsideration and allowance of this Application are respectfully requested.

At the outset it is noted that a shortened statutory response period of three (3) months was set in the May 13, 2003 Official Action. The initial due date for response, therefore, was August 13, 2003. A petition for a two month extension of the response period is presented with this response, which is being filed within the two month extension period.

In the May 13, 2003 official Action, claims 4-11, 13, 15, 17, and 18 are indicated as allowable if rewritten in independent form.

Additionally, at page 2 of the Official Action, the Examiner rejects claims 1-3, 12, 14, and 16 under 35 U.S.C. §102(b) as alleged being anticipated by Merianos et al. (U.S. Patent No. 5,209,922). This is the sole ground of the rejections set forth in the May 13, 2003 Official Action.

In accordance with the present amendment, claims 1-3 are canceled; claims 4, 12, 16, and 18 are amended; and new claims 19-26 are added. Accordingly claims 4-26 are currently pending in the present Application.

Claims 4 and 12 have been rewritten in independent form incorporating all the limitations recited in canceled claims 1 and 2, from which they were dependent. Additionally, claim 12 is further amended to recite that the composition of matter is formed in an aqueous medium and that the supramolecular complex has a particle size less than 500 nm. Support for these amendments can be found at pages 47-48 of the specification, wherein sodium phosphate buffer (SPB) or TRIS-buffer was used in Examples 13-16 to form a complex of the

type encompassed by claim 12, and at page 28, lines 30-31 of the specification, where it is disclosed that the preferred size of the complex is less than 500 nm.

Claim 16 is amended to depend from amended claim 4.

Claim 18 has been amended to delete the reference to canceled claim 1.

New claims 19 and 20 are directed to methods as claimed in claim 18 wherein the polyionic segment is polyanionic or polycationic, respectively. Support for these amendments can be found at page 3, lines 28-31 of the specification where it is disclosed that the polyionic segment may be polyanionic or polycationic.

New claims 21 and 22 incorporate all the limitations recited in canceled claim 3 but depend from claims 4 and 12, respectively.

New claims 23 and 24 are further directed to compositions as claimed in claim 12 wherein the particle size is less than 200 or 100 nm. Again, support for these recitations can be found at page 28, lines 30-31 of the specification.

New claims 25 and 26 incorporate all the limitations recited in original claims 16 and 17 but depend from claim 12.

In summary, the amended claims 4, 12, 16, and 18 and the newly added claims 19-26 are directed to particular embodiments of the present invention. No new matter is introduced by the present claim amendment, entry of which is respectfully requested.

In light of the foregoing amendment and the following remarks the above-noted rejection of claims 1-3, 12, 14, and 16 under 35 U.S.C. §102(b) based on Merianos et al. is respectfully traversed.

Amended Claim 4 And Its Dependent Claims (Claims 5-11, 16, 17, and 21) Are Allowable

As indicated in the present Official Action, original claims 4-11 and 17 are considered allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. By the present amendment, claim 4 is now amended to independent form incorporating all the limitations recited in canceled claims 1 and 2. Additionally, currently amended claim 16 and newly added claim 21 are both dependent from claim 4 and drawn to particular embodiments of the present invention, as noted above. Thus, it is Applicants' belief that claim 4 and its dependent claims, claims 5-11, 16, 17, and 21, as they presented hereinwith, are now in condition for allowance.

Amended Claim 18 And Its Dependent Claims (Claims 19 and 20) Are Now Allowable

The present Official Action also indicates that claim 18 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Again, by the present amendment claim 18 is now in independent form by canceling the reference to claim 1. New claims 19 and 20 that dependent from claim 18 are added to recite the method of claim 18 wherein the polyionic segment is polycationic or polyanionic, as noted above. Therefore, the amended claim 18 and its dependent claims, claims 19 and 20, are also in condition for allowance.

Amended Claim 12 And Its Dependent Claims (Claims 13-15 and 22-26) Are Patentably Distinguishable From Merianos et al.

It is the Examiner's position that Merianos et al. teach a block polymer comprising poly(vinyl lactam) units and quarternized amino alkyl acryl amide units, with the later being ionically bound to undecylenic acid. The Examiner

further asserts that claims 12, 14, and 16 are anticipated by Merianos et al. This rejection is respectfully traversed for the following reasons.

In order to constitute evidence of lack of novelty under 35 U.S.C. §102(b), a prior art reference must identically disclose each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

In the instant case, claim 12 has been amended to recite a composition of matter comprising a supramolecular complex which comprises as constituents a block copolymer, having at least one nonionic, water soluble segment and at least one polycationic segment, and at least one charged surfactant having hydrophobic groups, the charge of said surfactant being opposite to the charge of the polycationic segment of said block copolymer. Claim 12 further recites that i) the composition forms a supramolecular complex in an aqueous medium (see Examples 13-16 at pages 47-48 of the specification, wherein sodium phosphate buffer (SPB) or TRIS-buffer is used); ii) the constituents of the complex are bound by interactions between the opposite charges and between surfactant hydrophobic groups (see page 3, lines 20-23 of the specification); and iii) the complex has a particle size less than 500 nm (see page 28 lines 30-33 of the specification). None of these three recitations is taught or suggested by Marianos et al.

It is noteworthy that the polymer complex of Marianos et al. is formed in methanol, an organic solvent, see Example 1 at column 4 of Marianos et al. That being the case no interactions between the surfactant hydrophobic groups would occur in the complexes of Marianos et al. because the methanol environment would inhibit such interactions. This lack of interaction between surfactant hydrophobic groups in an alcohol-containing media is evidenced by the study of Khandurina et al. in "Stability of Polycomplexes of Cross-Linked Polyelectrolytes with Surfactants in Aqueous Salt and

Aqueous Organic Media", *Polymer Science* 1994;36(2):195,198, a copy of which is attached. In Khandurina et al., the authors investigated the stability of polymer-surfactant complexes (PSC) in aqueous salt and alcohol-containing media. Khandurina et al. teach that "the hydrophobic interaction between the aliphatic surfactant radicals contributes significantly to the stabilization of PSC in aqueous media". The authors found that "the weakening of hydrophobic contacts in the PSC species upon going from aqueous to aqueous organic media will facilitate the dissociation of the complex". Moreover, "[t]he dissociation of PSC ... in an aqueous alcohol media is accompanied by a sharp increase in the degree of swelling *H* of the complexes (by one order of magnitude or even greater)." In summary, it is clear that the "interaction between surfactant hydrophobic groups", which is called for in amended claim 12, would not occur in the block copolymers described in Marianos et al., as they are prepared in a methanol medium.

Further, as disclosed at page 28, lines 22-35 of the present specification, the compositions of the present invention normally form complexes of small size, preferably less than 500 nm, which is important because small particles can easily penetrate into tissues through even small capillaries and enter cells via endocytosis. Although it is stated in Example 1 of Marianos et al. that during the formation of the complex, "[t]he solution were heated to about 55°C and mixed for 2 hours to provide a hazy suspension of fine particles", it is noted that this suspension of fine particles was formed in methanol. Also in Example 1 of Marianos et al., it is stated that the mixture with fine particles was further evaporated to remove methanol and dried under vacuum. Accordingly, it is unlikely that these fine particles would survive such processing, and be still present in the final dry form of the complex. It should also be noted

that a small particle size is not required for the end uses described in Marianos et al., i.e. powder, dust, moisturizing cream, foot cream, aerosol foot powder, aerosol powder, and dry powder stick.

In conclusion, Marianos et al. fails to disclose each and every element of claim 12. Therefore, the rejection of claim 12 under U.S.C. §102(b) based on Merianos et al. should be withdrawn and claim 12, as it is presently amended, should be allowed. Furthermore, inasmuch as claims 13-15 and new claims 22-26 are dependent from claim 12 and directed to particular embodiments of the composition recited in claim 12, these claims should also be allowed.

Conclusion

In view of the amendments and remarks presented herewith, it is respectfully urged that the objections and rejections set forth in the May 13, 2003 Official Action be withdrawn and that this application be passed to issue. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any issues outstanding may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given above.

Respectfully submitted,

DANN DORFMAN HERRELL and SKILLMAN, P.C.

Attorneys for Applicant

By Patrick J. Hagan
Patrick J. Hagan
Registration No. 27,643

Enclosure:

- Khandurina et al. *Polymer Science* 1994;36(2):195,198